DEC 1 4 2001

K013151
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

BKG Opthalmics USA, Inc.
7334 Hollister Ave., Suite I
Goleta, CA 93117

Phone: 805-685-9991
Fax: 805-685-1292

Contact Person: Les Vorosmarthy

Date of Summary: October 29, 2001

Trade Name: ASMOTOM Automated Trephine System

Classification Name: Trephine, AC-Powered

Product Code: HRG

Regulation Number: 886.4070

Predicate Device: Summit Technology K-B Microkeratome K980675

Intended Use: The ASMOTOM Automated Trephine System is intended to perform penetrating cuts of the central portion of the cornea. The Primary and only purpose of this device is to produce cuts necessary for the corneal transplantation.

Device Comparison Chart

Feature	BKG Ophthalmic ASMOTOM	Summit K-B Microkeratome
Indications for Use	Keratoplasty	Same
Method of cut	Automatic – to preset depth	Automatic – Step motor controlled 0.1 to 3.0mm/sec.
Materials (Patient Contact)	Stainless Steel and Brass	Stainless Steel, Plastic, Glass, Natural Diamond
Blade Oscillation	Adjustable. Patient preset available	Adjustable. with preset default
Manufacturer	Deutschmann - Medizintechnik	Gebauer GMBH
Motor	12 V	12 V
Speed	16,500 RPM	5,000 – 20,000 RPM
Weight	200 g	N/A
Power Supply	90 V – 240 V	100 V – 240 V
Frequency	50 – 60 Hz	Same
Vacuum	0 – 800 mbar	0 – 1.0 bar
Suction Rings	Yes	Yes
Blades	6.0 mm - 8.2 mm	Various
Off-Set Rings	0.2 mm – 1.2 mm	Programmable
Hand Switch	Yes	Yes
Foot Switch	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

BKG Opthalmics USA, Inc.
c/o Mr. Arthur Ward, Consultant
962 Allegro Lane
Apollo Beach, FL 33572

Re: K013151
Trade/Device Name: ASMOTOM Automated Trephine System
Regulation Number: 21 CFR 886.4070
Regulation Name: Trephine, AC-Powered
Regulatory Class: I
Product Code: HRG
Dated: November 9, 2001
Received: November 13, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): _____

Device Name: ASMOTOM Automated Trephine System

Indications For Use:

The ASMOTOM Automated Trephine System is intended to perform penetrating cuts of the central portion of the cornea. The purpose of this device is to produce cuts necessary for the corneal transplantation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Daniel L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013151